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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/077,817	09/14/1998	DANIEL CAPUT	IVD924	6529

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EXAMINER	
BASI. NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/077,817	**Applicant(s)** CAPUT ET AL.	
	Examiner Nirmal S. Basi	**Art Unit** 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on *16 December 2004*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *44-47,72,73,75-78,86,87 and 111-114*.
   Claim(s) withdrawn from consideration: *5-36,38,52-71 and 89-110*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 3. NOTE: The inclusion of the specific stringent hybridization conditions in claims 78, 81, and 111 would require a new consideration under 35 USC112, first paragraph and a new search of the prior art.

Continuation of 11. does NOT place the application in condition for allowance because: Applicants proposed amendments would overcome the rejections under 35 USC 112, second paragraph. It is acknowledged claim 85 is cancelled. Claims 44, 46-47, 72-73, 75-78, 81, 83-84, 86-87,111-114 would remain rejected under 35 U.S.C. 112, first paragraph for reasons of record (4/16/2004). In brief the rejected claims pertain to polypeptides, with no disclosed biological activity, comprising fragments of the polypeptide disclosed in the amino acid of sequence of SEQ ID NO:2.

The polypeptides, as claimed, embrace compounds which may be unrelated to the protein of SEQ ID NO:2. Without disclosure of where specially, in the structure of the polypeptide, the critical feature on the invention is contained, it accordingly follows that the specification does not adequately teach how to make or use a commensurate number of polypeptides comprising fragments, with no associated biological activity, of the polypeptide disclosed in SEQ ID NO:2. Further the product by process claims may produce protein completely unrelated to the receptor of SEQ ID NO:2. Nucleic acids, not encoding the critical feature of the receptor of SEQ ID NO:2, are also produced using the method as claimed. For example, hybridization conditions may lead to isolation of nucleic acids which encode polypeptides unrelated to the protein of SEQ ID NO: 2. Applicant has not disclosed how to use said protein/fragments. Many said protein variants may be inactive. Due to the large quantity of experimentation necessary to identify the polypeptides instant invention containing the critical feature of the invention, the lack of direction/guidance presented in the specification regarding the identification, purification, isolation and characterization of said polypeptide the unpredictability of the effects of mutation on the structure and function of proteins, and the breadth of the claim which fail to recite sufficient structural limitations encompassing the critical feature of the invention, undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

Further, claims 44, 47, 72-73, 75-78, 81, 83-84 and 86-87, 111-114 remain rejected under 35 U.S.C. 112, first paragraph for reasons of record, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed. Again, the rejected claims pertain to polypeptides, with no disclosed biological activity, comprising fragments of the polypeptide disclosed in the amino acid of sequence of SEQ ID NO:2. The polypeptides, as claimed, embrace compounds which may be unrelated to the protein of SEQ ID NO:2. The disclosure of the distinct polypeptide of SEQ ID NO:2 (380 amino acids) does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length, truncated, fusion polypeptides and variants thereof comprising said polypeptides. There is no description of the conserved regions, which are critical to the structure and function of the genus claimed or which sequences may be biologically active and what is that biological activity. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed and predict their use. Further no identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. Accordingly, an adequate written description of a protein is more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the protein itself.

Nirmal S. basi